

Since January 2020 Elsevier has created a COVID-19 resource centre with free information in English and Mandarin on the novel coronavirus COVID-19. The COVID-19 resource centre is hosted on Elsevier Connect, the company's public news and information website.

Elsevier hereby grants permission to make all its COVID-19-related research that is available on the COVID-19 resource centre - including this research content - immediately available in PubMed Central and other publicly funded repositories, such as the WHO COVID database with rights for unrestricted research re-use and analyses in any form or by any means with acknowledgement of the original source. These permissions are granted for free by Elsevier for as long as the COVID-19 resource centre remains active.



ScienceDirect

Contents lists available at **sciencedirect.com** Journal homepage: **www.elsevier.com/locate/jval**

Themed Section: COVID-19

Evidence of Stability in Patient-Reported Global Health During the COVID-19 Pandemic

Brittany R. Lapin, PhD, Wai Hong Wilson Tang, MD, Ryan Honomichl, PhD, Olivia Hogue, MPH, Irene L. Katzan, MD

ABSTRACT

Objectives: Measures of health-related quality of life (HRQOL) are collected throughout healthcare systems and used in clinical, economic, and outcomes studies to direct patient-centered care and inform health policy. Studies have demonstrated increases in stressors unique to the COVID-19 pandemic, however, their effect on HRQOL is unknown. Our study aimed to assess the change in self-reported global health during the pandemic for patients receiving care in a large healthcare system compared with 1 year earlier.

Methods: An observational cross-sectional study of 2 periods was conducted including adult patients who had a healthcare appointment and completed the Patient-Reported Outcomes Measurement Information System Global Health (PROMIS GH) as standard care during the COVID-19 pandemic and a year earlier. The effect of time on PROMIS global mental health (GMH) and global physical health (GPH) was evaluated through multiple statistical methods.

Results: There were 38 037 patients (mean age 56.1 \pm 16.6 years; 61% female; 87% white) who completed the PROMIS GH during the pandemic (August 2020) and 33 080 (age 56.7 \pm 16.5 years; 61% female; 86% white) who had completed it 1 year earlier (August 2019). GMH was significantly worse, whereas GPH was similar during the pandemic compared with a year earlier (adjusted estimate [standard error]: -1.21 (0.08) and 0.11 (0.08) T-score points, respectively).

Conclusions: Our study found modest, nonclinically meaningful decreases in GMH and similar GPH during the COVID-19 pandemic compared with a year earlier in patients cared for in a large healthcare system. Nevertheless, healthcare systems are likely seeing a biased sample of patients during these times. Findings from our study have implications for the interpretation of HRQOL during this pandemic.

Keywords: COVID-19, health-related quality of life, health system.

VALUE HEALTH. 2021; 24(11):1578-1585

Introduction

Patient-reported outcomes (PROs) are used in the clinical management and evaluation of patient outcomes and have important implications across multiple areas of healthcare. At the individual level, PROs provide important information about the effect of medical therapies beyond that of traditional clinical outcomes.^{1–3} At the organizational level, regulatory agencies incorporate the patient's perspective when evaluating comprehensive quality care and informing health policy.^{4,5} One key area of PRO measurement is health-related quality of life (HRQOL), which reflects the impact of health conditions and treatments on disability and daily functioning.⁶ The Patient-Reported Outcomes Measurement Information System Global Health (PROMIS GH) was developed by the National Institutes of Health as a publicly available standardized global health assessment tool and is used to measure HRQOL across healthcare systems and in large epidemiologic surveys.^{7–11}

With the abrupt and dramatic alteration of daily life because of the onset of the COVID-19 pandemic in spring 2020, most US residents had significant concerns about contracting the virus and anxiety of the longstanding economic impact.¹² Overall wellbeing was threatened by aspects of the pandemic, including social isolation, decreased social support, economic uncertainty, greater inactivity, and less access to basic services.^{13,14} Although several studies have demonstrated increased rates of anxiety, depression, and posttraumatic stress disorder symptoms as a result of stressors unique to COVID-19,^{15–24} the impact on overall HRQOL for patients seen in a healthcare system is unknown.

Furthermore, healthcare delivery in the United States has also been significantly transformed with rapid transition from inperson to virtual medical visits to reduce the risk of transmission of COVID-19 to patients. As healthcare transitioned to this primarily virtual environment, the types of patients seeking care and completing measures of HRQOL are likely different, which could potentially bias estimates of HRQOL in research studies and policy initiatives. The variation in reported global health during these times could have a substantial impact on the interpretation of PROMIS GH across health systems.



To evaluate the impact of the COVID-19 pandemic on HRQOL at large in the healthcare system, our study aimed to examine PROMIS GH in cohorts of patients receiving ambulatory care during the pandemic compared with those who were receiving it a year ago.

Methods

We conducted an observational cross-sectional study of 2 periods including all adult patients who completed the PROMIS GH at Cleveland Clinic in northeast Ohio during the pandemic (August 2020) compared with those who completed it a year ago (August 2019). August was chosen as the month for data retrieval because it is when practice patterns stabilized and PROMIS GH deployed data was linked for virtual visit types implemented during the pandemic. Patient-reported information, including the PROMIS GH, was collected through an electronic platform²⁵ and was available in the electronic health record (EHR) at the point of care. PROs were administered either on tablets immediately before an ambulatory patient visit or at home before their appointment via a patient portal (MyChart, Epic Systems, Verona, WI).

Patients completed the 10-item PROMIS GH as a part of standard care. PROMIS GH includes 10 items, with 9 of the items scored on a Likert scale from 1 to 5, with 5 representing the best response. One item (pain intensity) is answered on a scale from 0 to 10, but was recoded to a 5-point scale as recommended in the scoring manual.²⁶ PROMIS GH produces 2 summary scores: global mental health (GMH) and global physical health (GPH).²⁷ GMH consisted of 4 items on overall quality of life, mental health, satisfaction with social activities and relationships, and emotional problems, whereas GPH includes 4 items on physical health, physical functioning, pain, and fatigue. Two items (general health and ability to perform social roles) were not used to calculate the summary scores. GMH and GPH summary scores were centered on the 2000 US Census and transformed to a T-score metric with a mean of 50 and standard deviation of 10.28 Clinically meaningful differences in PROMIS GH were estimated to lie between 2 and 5 T-score points.²⁹

Patient demographics were extracted from the EHR and included age, self-reported race, sex, marital status, insurance status, and household income estimated from 2010 census data by zip code. Clinical characteristics included the Charlson comorbidity index (a measure of 19 conditions related to the potential for mortality and morbidity)³⁰ and binary indicators for emergency department use or hospitalization in the previous 6 months. Additional variables related to the visit included clinical center associated with PROMIS GH completion, new versus established visit to that center, and method of questionnaire completion (MyChart vs electronic tablet at the office visit). The study was approved by the institutional review board. Because the study consisted of analyses of preexisting data, the requirement for a patient informed consent was waived.

Statistical Analysis

Patient and visit characteristics and PROMIS GH summary scores and items were summarized using descriptive statistics and compared across cohorts (during the pandemic vs 1 year ago) using chi-square test for categorical variables and t-test or Mann– Whitney U test, as appropriate, for continuous variables.

Owing to circumstances of the pandemic, it was hypothesized patients seeking healthcare during this time were likely different from those seen in 2019. Therefore, multivariable models, propensity score (PS) matching, and inverse probability of treatment weighting (IPTW) were used to estimate cohort differences on PROMIS GH. The primary analysis modeled the effect of time on PROMIS GH summary scores using multivariable linear regression, adjusting for potential confounders (listed in Table 1). Additionally, the 10 items comprising the PROMIS GH were modeled using both ordinal logistic regression and linear regression. Ordinal logistic regression was conducted after assumptions of proportional odds were tested and met. Both models yielded similar results, so estimates were presented from linear regression models for ease of interpretability. Interaction terms were included in multivariable models to identify patient characteristics associated with a differential reduction in PROMIS GH in 2020. Because the pandemic has disproportionately affected racial and ethnic minority groups and those with lower socioeconomic status, interaction effects between time period and race and time period and tertile of income were included in the models.

In secondary analyses, additional statistical methods were applied to evaluate the robustness of estimates of effect of time period on PROMIS GH. PS matching was performed to reduce group selection bias because of confounding factors that could be associated with time. PSs for the probability of being seen during the pandemic versus 1 year ago were estimated with a multivariable logistic regression model including all variables in Table 1, with the exception of MyChart (vs in-person tablet) completion. This was not included because the vast majority of patients seen during the pandemic completed the PROMIS GH through MyChart, which significantly limited the number of available matches. The greedy nearest neighbor method matched 1 patient from 2020 to 1 patient from 2019 using the smallest within-pair difference between the logit of the PSs.³¹ A stringent caliper of 0.01 was required, and all matched pairs were exact matches on medical center. In the matched sample, balance of covariates was assessed between patients seen during the pandemic and 1 year earlier using standardized mean differences.³² Any variables with differences >0.10 were included in subsequent models.³³ PROMIS GH summary scores were modeled using repeated measures generalized linear models with the inclusion of the match identifier.

Finally, a separate set of analyses were weighted using IPTW. The weights were calculated as the marginal probability of completing PROMIS GH during the pandemic given no covariates divided by the PS (as defined above) versus completing PROMIS GH in 2019 (IPTW = 1/PS for patients seen during the pandemic and 1/1-PS for patients seen in 2019). Covariate balance was established by examining the weighted standardized mean differences between patients seen during the pandemic and 1 year ago. PROC CAUSALTRT in SAS was used with augmented inverse probability weights to perform doubly robust estimation of the average effect of time period on PROMIS GH.³⁴ With this method, the average effect of time period on PROMIS GH summary scores was estimated in weighted generalized linear models with bootstrapped variance estimation. For the secondary analyses of PS matching and IPTW, PROMIS GH items were modeled as both continuous variables and as ordinal variables using a cumulative logit link function. As results were similar between both models, estimates were presented from models treating items as continuous variables.

Statistical analyses were conducted using SAS version 9.4 (SAS Institute Inc, Cary, NC) at a significance level of 0.05. Because the results of our study are exploratory and focused on estimates of effect, there was no formal adjustment for multiple comparisons.

Sensitivity and Validation Analyses

Two sensitivity analyses were conducted to evaluate the consistency of the relationship between time period and PROMIS GH. The first sensitivity analysis limited the cohort to the subset of patients who completed the PROMIS GH in the same conditionbased centers in both August 2019 and August 2020. PROMIS GH was compared between years through generalized linear models with the inclusion of the patient identifier and adjusting for

Table 1. Characteristics of patients who completed the PROMIS GH by time period.

Patient characteristics	During the COVID-19 pandemic, n (%)	One year earlier, n (%)	P value			
Total number of visits	38037 (53.5)	33 080 (46.5)				
Female sex	23296 (61.3)	20218 (61.1)	.715			
Age, mean (SD)	56.1 (16.6)	56.7 (16.5)	<.001			
Race			<.001			
White	32356 (87.4)	27 502 (85.9)				
Black	3322 (9.0)	3365 (10.5)				
Other	1348 (3.6)	1149 (3.6)				
Marital status			<.001			
Married	24007 (63.6)	20082 (61.4)				
Single	8995 (23.8)	8171 (25.0)				
Divorced	2851 (7.6)	2628 (8.0)				
Widowed	1883 (5.0)	1839 (5.6)				
Median household income (per \$10 000), (q1, q3)	5.8 (4.5, 7.2)	5.7 (4.4, 7.1)	<.001			
Insurance			<.001			
Private	21 592 (56.8)	17 133 (51.8)				
Medicare	13221 (34.8)	12700 (38.4)				
Medicaid	2642 (7.0)	2377 (7.2)				
Self-pay	582 (1.5)	870 (2.6)				
Charlson comorbidity index, median (q1, q3)	1 (0, 4)	2 (0, 4)	.044			
PROMIS GH completed via MyChart (vs in office)	36 267 (95.4)	16 100 (49.8)	<.001			
Established patient visit (vs new visit in center)	31 513 (82.9)	23 838 (72.1)	<.001			
Center			<.001			
Brain health	229 (0.6)	218 (0.7)				
Cerebrovascular	162 (0.4)	152 (0.5)				
Cancer	3594 (9.5)	2991 (9.0)				
Cardiac	824 (2.2)	396 (1.2)				
Epilepsy	138 (0.4)	279 (0.8)				
Functional medicine	852 (2.2)	896 (2.7)				
Headache	862 (2.3)	834 (2.5)				
Internal/family medicine	20654 (54.3)	12953 (39.2)				
Multiple sclerosis	422 (1.1)	660 (2.0)				
Neurorestoration	598 (1.6)	319 (1.0)				
Neurology	1068 (2.8)	925 (2.8)				
Neuromuscular	190 (0.5)	224 (0.7)				
Physical/occupational therapy	2845 (7.5)	4014 (12.1)				
Pain—neurological	488 (1.3)	1416 (4.3)				
Psychology/psychiatry	771 (2.0)	481 (1.5)				
Rheumatology	1907 (5.0)	2801 (8.5)				
Sleep	492 (1.3)	394 (1.2)				
Spine	1214 (3.2)	2161 (6.5)				
Other	727 (1.9)	966 (2.9)				
Emergency department visit in last 6 months	4938 (13.0)	4952 (15.0)	<.001			
Hospitalization in last 6 months	2275 (6.0)	2340 (7.1)	<.001			
<i>Vote.</i> During the COVID-19 pandemic, data from August 2020 compared with 1 year earlier (August 2019).						

GH indicates Global Health; PROMIS, Patient-Reported Outcomes Measurement Information System; q, quartile; SD, standard deviation.

Table 2. PROMIS GH by period.

PROMIS GH summary scores and items	Question	During the COVID-19 pandemic		One year earlier		<i>P</i> value
			Mean (SD)		Mean (SD)	
GMH T-score	-	37 469	47.95 (9.13)	32 905	48.47 (9.49)	<.001
GPH T-score	-	37 458	47.33 (9.04)	32616	45.80 (9.37)	<.001
GH items						
1. General health	In general, would you say your health is:	37 915	3.17 (0.95)	32 997	3.14 (0.96)	<.001
2. Quality of life*	In general, would you say your quality of life is:	37 884	3.49 (0.99)	33 000	3.46 (1.02)	.002
3. Physical health [†]	In general, how would you rate your physical health?	37 936	3.04 (0.97)	33 034	3.04 (0.98)	.416
4. Mental health*	In general, how would you rate your mental health, including your mood and your ability to think?	37 886	3.37 (1.03)	33 037	3.48 (1.05)	<.001
5. Social discretionary*	In general, how would you rate your satisfaction with your social activities and relationships?	37 865	3.32 (1.07)	33 034	3.43 (1.11)	<.001
6. Physical function [†]	To what extent are you able to carry out your everyday physical activities such as walking, climbing stairs, carrying groceries, or moving a chair?	37 895	4.16 (1.09)	33 039	3.97 (1.15)	<.001
7. Pain [†]	In the past 7 days, how would you rate your pain on average?	37 831	3.75 (0.98)	32 737	3.52 (1.05)	<.001
8. Fatigue [†]	In the past 7 days, how would you rate your fatigue on average?	37 867	3.61 (0.93)	32 952	3.49 (0.94)	<.001
9. Social roles	In general, please rate how well you carry out your usual social activities and roles. (This includes activities at home, at work, and in your community and responsibilities as a parent, child, spouse, employee, friend, etc.)	37 740	3.40 (1.06)	33 002	3.43 (1.11)	<.001
10. Emotional problems*	In the past 7 days, how often have you been bothered by emotional problems such as feeling anxious, depressed, or irritable?	37 896	3.52 (1.06)	33 035	3.50 (1.04)	.019

Note. GH items on a scale from 1 to 5 where higher scores indicate better health-related quality of life.

GH indicates Global Health; GMH, global mental health; GPH, global physical health; PROMIS, Patient-Reported Outcomes Measurement Information System; SD, standard deviation.

*Questions comprise PROMIS GMH summary score.

[†]Questions comprise PROMIS GPH summary score.

covariates from the pandemic-era visit. Second, because most patients during the pandemic completed the PROMIS GH electronically through MyChart, a sensitivity analysis was conducted only for patients who completed the PROMIS GH using MyChart in each cohort. PROMIS GH summary scores and items were modeled using multivariable linear regression adjusting for patient demographics and visit characteristics.

Finally, a validation analysis was conducted to evaluate the annual difference in PROMIS GH scores prepandemic, in January and February. Multivariable models as described earlier were constructed to assess the change in PROMIS GH from January and February 2019 to January and February 2020.

Results

There were 38 037 unique patients who completed PROMIS GH during the pandemic and 33 080 unique patients who completed it 1 year ago (Table 1). In both periods, most patients completing the

PROMIS GH scale were female, white, and married. Compared with patients seen 1 year earlier, patients seen during the COVID-19 pandemic were slightly younger (mean age 56.1 years [standard deviation 16.6] vs 56.7 years [standard deviation 16.5]) and more often had private insurance (56.8% vs 51.8%), higher median income (median \$57 587 vs \$56 832), and fewer comorbidities (median 1 vs 2). The vast majority of patients completed the PROMIS GH electronically via MyChart in 2020 (95.4% vs 49.8% in 2019). Patients seen during the pandemic were also more likely to be established patients in the clinical center compared with patients seen 1 year earlier (82.9% vs 72.1%) and less likely to have had an emergency department visit or hospitalization in the past 6 months (13% vs 15% and 6% vs 7%, respectively).

The average PROMIS GH summary and item scores are presented in Table 2. The average unadjusted PROMIS GMH and GPH were 48.0 (9.1) and 47.3 (9.0) for patients seen during the pandemic and 48.5 (9.5) and 45.8 (9.4) for patients seen 1 year earlier, respectively.

PROMIS GH summary scores and items	Multivariable models [‡]		PS matched mod (24789 pairs)	PS matched models (24789 pairs)		Estimations using IPTW	
	Estimate (SE)	P value	Estimate (SE)	P value	Estimate (SE)	P value	
GMH T-score	-1.208 (0.080)	<.001	-1.331 (0.081)	<.001	-1.283 (0.095)	<.001	
GPH T-score	0.111 (0.075)	.135	-0.094 (0.076)	.216	0.071 (0.091)	.468	
GH items							
1. General health	-0.054 (0.008)	<.001	-0.066 (0.008)	<.001	-0.070 (0.010)	<.001	
2. Quality of life*	-0.082 (0.009)	<.001	-0.097 (0.009)	<.001	-0.100 (0.011)	<.001	
3. Physical health [†]	-0.076 (0.008)	<.001	-0.100 (0.009)	<.001	-0.087 (0.010)	<.001	
4. Mental health*	-0.161 (0.009)	<.001	-0.162 (0.009)	<.001	-0.171 (0.011)	<.001	
5. Social discretionary*	-0.181 (0.009)	<.001	-0.204 (0.010)	<.001	-0.197 (0.012)	<.001	
6. Physical function [†]	-0.007 (0.009)	.453	-0.009 (0.009)	.324	-0.009 (0.012)	.436	
7. Pain [†]	0.074 (0.008)	<.001	0.059 (0.008)	<.001	0.082 (0.011)	<.001	
8. Fatigue [†]	0.051 (0.008)	<.001	0.028 (0.008)	<.001	0.048 (0.010)	<.001	
9. Social roles	-0.146 (0.009)	<.001	-0.158 (0.009)	<.001	-0.159 (0.011)	<.001	
10. Emotional problems*	-0.023 (0.009)	.011	-0.031 (0.009)	<.001	-0.007 (0.012)	.524	

Table 3. Estimation of the effect of period (during the COVID-19 pandemic vs 1 year earlier) on PROMIS GH.

Note. Estimate and SE presented for the COVID-19 pandemic (vs 1 year earlier); negative estimates indicate worse health-related quality of life in 2020 than in 2019. GH indicates Global Health; GMH, global mental health; GPH, global physical health; IPTW, inverse probability of treatment weighting; PROMIS, Patient-Reported Outcomes Measurement Information System; PS, propensity score; SE, standard error.

*Questions comprise PROMIS GMH summary score.

[†]Questions comprise PROMIS GPH summary score.

^{*}Multivariable models adjusted for all variables listed in Table 1.

The effect of time period on PROMIS GH after adjusting for selection bias was evaluated using 3 methods (Table 3). In the primary analysis, PROMIS GMH T-scores for patients cared for during the pandemic were significantly worse than those cared for 1 year ago, while GPH T-scores were similar (estimate [standard error [SE]]: -1.21 [0.08] and 0.11 [0.08], respectively) after adjustment for demographics and clinical characteristics. In secondary analyses, PS matching resulted in 24789 matched pairs between 2019 and 2020. Matching minimized differences across demographics and clinical characteristics (all standardized differences <0.09). Results were consistent, with significantly worse GMH and similar GPH scores in 2020 than 2019 (estimate [SE]: -1.33 [0.08] and -0.09 [0.08], respectively). Using IPTW, GMH T-score estimates were 47.7 (95% confidence interval [CI] 47.5-47.8) in 2020 compared with 49.0 (95% CI 48.6-49.1) in 2019 for an estimated difference of -1.28 (0.10). Adjusted GPH T-score estimates were similar in 2020 and 2019 (46.7 [95% CI 46.6-46.9] and 46.6 [95% CI 46.5-46.7]; estimated difference 0.07 [0.09]). Item analysis showed that most scores were significantly worse for patients cared for during the pandemic than those cared for 1 year ago, while pain intensity and fatigue were better.

In multivariable linear regression models, patients more likely to have worse GMH during the pandemic than 1 year ago were younger, were female, had lower income, had more comorbidities, and were seen in certain centers (including internal medicine, cancer, psychiatry, and epilepsy) (data available upon request). GMH T-scores were differentially worse in younger patients and those seen in certain centers (see Appendix Figure 1A,B in Supplemental Materials found at https://doi.org/10.1016/j.jval.2021. 06.009). There were no meaningful interaction terms between time period and characteristics for GPH.

There was not a significant interaction effect between time period and race (see Appendix Fig. 2A,B in Supplemental Materials found at https://doi.org/10.1016/j.jval.2021.06.009) or time period and income (see Appendix Fig. 3A,B in Supplemental Materials found at https://doi.org/10.1016/j.jval.2021.06.009). Nevertheless, black patients had significantly worse GMH and GPH at both time periods than white patients. Similarly, those with the lowest tertile of income had significantly worse GMH and GPH at both time points than those in the middle and upper tertiles of income.

Study results remained consistent in sensitivity analyses. There were 2725 patients who completed the PROMIS GH in both August 2019 and August 2020 in the same medical centers. For these patients, PROMIS GMH worsened, whereas GPH improved from 2019 to 2020 (estimate [SE]: -1.25 [0.13] and 0.33 [0.12], respectively) (Table 4). Social discretionary, social roles, and mental health items worsened the most, while pain and fatigue improved in 2020 compared with 2019. In a second sensitivity analysis of 52 367 (74%) patients from both cohorts who completed the PROMIS GH through MyChart, results remained consistent with those reported in the adjusted multivariable models from the full cohort (Table 3).

In a validation analysis, there were 30573 patients who completed the PROMIS GH in January 2019 and 47565 patients in January 2020 (data available upon request). After adjustment, GMH was worse in 2020 than in 2019 (estimate -0.507 [SE 0.068], P<.001), while GPH remained consistent (estimate 0.025 [SE 0.061], P=.680). In February, there were 27726 patients with completed PROMIS GH in 2019 and 39555 patients in 2020. After adjustment, GMH scores were also worse in February 2020 than in 2019 (estimate -0.406 [SE 0.073], P<.001), while GPH scores improved (estimate 0.172 [SE 0.066], P=.009).

Discussion

Our study of 71117 patients in a large healthcare system found modest declines in GMH scores in patients cared for during the Table 4. Sensitivity analyses: estimation of the effect of period (during the COVID-19 pandemic vs 1 year earlier) on PROMIS GH.

PROMIS GH summary scores and items	Sensitivity analysis 1 and 2020 (N = 2725)	l: both 2019	Sensitivity analysis 2: MyChart completion (N = 52 367)		
	Estimate (SE)	<i>P</i> value	Estimate (SE)	<i>P</i> value	
GMH T-score	-1.253 (0.127)	<.001	-1.149 (0.086)	<.001	
GPH T-score	0.329 (0.119)	.006	0.109 (0.081)	.178	
GH items					
1. General health	-0.022 (0.014)	.130	-0.043 (0.009)	<.001	
2. Quality of life*	-0.094 (0.014)	<.001	-0.066 (0.009)	<.001	
3. Physical health [†]	-0.055 (0.014)	<.001	-0.068 (0.009)	<.001	
4. Mental health*	-0.146 (0.016)	<.001	-0.151 (0.010)	<.001	
5. Social discretionary*	-0.222 (0.017)	<.001	-0.168 (0.010)	<.001	
6. Physical function [†]	0.005 (0.015)	.756	-0.010 (0.010)	.299	
7. Pain [†]	0.066 (0.016)	<.001	0.070 (0.009)	<.001	
8. Fatigue [†]	0.087 (0.015)	<.001	0.048 (0.009)	<.001	
9. Social roles	-0.163 (0.017)	<.001	-0.131 (0.010)	<.001	
10. Emotional problems*	0.003 (0.017)	.884	-0.038 (0.010)	<.001	

Note. Estimate and SE presented for the COVID-19 pandemic (vs 1 year earlier); negative estimates indicate worse health-related quality of life in 2020 than 2019. Sensitivity analysis 1 conducted for patients who completed the PROMIS GH in both August 2019 and August 2020 in the same medical centers. Models adjusted for all variables in August 2020 listed in Table 1; sensitivity analysis 2 conducted for patients who completed the PROMIS GH via MyChart in August 2019 or August 2020. Models adjusted for all variables listed in Table 1 (except MyChart completion).

GH indicates Global Health; GMH, global mental health; GPH, global physical health; PROMIS, patient-reported outcomes measurement information system; SE, standard error.

*Questions comprise PROMIS GMH summary score.

[†]Questions comprise PROMIS GPH summary score.

COVID-19 pandemic compared with those cared for 1 year ago. In contrast, patients showed similar GPH across the 2 periods. Adjusted estimates of the difference in GMH and GPH were – 1.21 and 0.11 T-score points, respectively, during the pandemic compared with 1 year ago—much smaller than generally accepted meaningful differences in T-scores.²⁹

Although research studies have highlighted the potential of COVID-19 to significantly affect anxiety and depression,^{15,19,22-24} to our knowledge, our study is the first to evaluate global health at the population-level. There are several potential reasons for the differences in previous studies demonstrating clinically meaningful increases in anxiety and depression during COVID-19 compared with our current study finding minimal decreases in GMH. Most of the previous reports involved additional data collection for a research study, whereas our study consisted of routinely collected data over time. Almost all previous research focused on symptoms of depression, anxiety, and stress, whereas our study evaluated broader constructs of HRQOL. Importantly, most of the previous studies involved cross-sectional surveys of the general population or patients who received a diagnosis of COVID-19, whereas our study involved patients receiving care in a large health system. Our results indicate HRQOL of people receiving healthcare may not be as strongly affected as previously thought.

Studies of factors associated with increased anxiety and depression during COVID-19 have included female sex, younger age, lower income, and more comorbidities.^{13,21,23,24} Our study also found worse GMH associated with female sex, younger age, black or African American race, lower income, and more comorbidities, and although scores were significantly worse during the pandemic than they were 1 year ago, they were only slightly differentially worse for younger patients. Several studies evaluating emotional symptoms during the COVID-19 pandemic have

shown increased depression, anxiety, and posttraumatic stress disorder symptoms as a result of stressors unique to COVID-19 including fear of illness and negative economic effects.^{15–22,35–37} In addition to increases in stress and depression, studies have noted that the impact of the pandemic on daily life could additionally lead to negative consequences for diet, physical activity, and other aspects of self-care.^{13,38,39} Our study suggests this may not be as large of an issue for patients seen in ambulatory care because GPH and the items comprising the summary score were similar in 2020 and 2019.

Our study also provides some insights into which aspects of global health are most affected as a result of the COVID-19 pandemic. The responses to the majority of individual items that comprise PROMIS GH were worse during the pandemic than 1 year earlier. Not surprisingly, satisfaction with social activities and relationships experienced the greatest decline, although average adjusted scores of 3.3 (of 5) indicate patients are still generally satisfied with this area of their life. Pain intensity and fatigue were better during the COVID-19 pandemic than in 2019. This could be due to reductions in work-related and recreational activities outside the home as a consequence of COVID-19. Our research highlights topical domains to monitor in patients during and after the COVID-19 pandemic; patient satisfaction with social roles and activities may improve as sequelae of the pandemic abate, whereas fatigue may worsen once activities normalize.

Although our study adjusted for known differences, the types of patients cared for during the COVID-19 era differed from those cared for in the year before. There was a rapid transition from inperson to virtual medical visits to reduce the risk of transmission of COVID-19 to patients, with many healthcare systems launching electronic platforms to monitor patient symptoms remotely.⁴⁰ Patients may have been hesitant to seek healthcare during the

pandemic due to fear of COVID-19 infection or financial concerns that have arisen or been exacerbated by the COVID-19 pandemic. In addition, patients experiencing social or economic turmoil from the COVID-19 pandemic may have made healthcare a lower priority. Patients who were less comfortable with technology, had no or limited access to internet, or did not use smart devices may have been less apt to participate in virtual visits.^{41–43} A recent report from the Centers for Disease Control and Prevention found more than 40% of American adults have put off medical care with routine and urgent care avoidance more likely in patients older than 44 years, people with higher education, people with chronic health conditions, racial and ethnic minority groups, and those without health insurance.⁴⁴ Thus, it is possible that HRQOL is worse in the patients in our health system who did not seek care during COVID-19, and our findings support the approach of outreach efforts to patients who have not interacted with the health system during the pandemic. Nevertheless, the results of our study, including several confirmatory and sensitivity analyses, suggest that measures of HRQOL collected as part of routine care in health systems may have only a modest decline due to COVID-19. These results have implications for interpreting HRQOL scores collected in clinical practice that span periods before and during the COVID-19 pandemic. Based on our study findings, research studies or quality initiatives using PROMIS GH data over this period should not be substantially biased although analyses should be adjusted for the types of patients seen during these months.

Our study has many strengths including rigorous statistical methodology and a large sample of patients seeking medical care in the United States. Most patients seen during the COVID-19 pandemic were seen in internal or family medicine departments, which increases the generalizability of study results. The validity of the cohort analysis is demonstrated through analyzing differences in PROMIS GH between January 2019 and 2020 and February 2019 and 2020. Although GMH decreased in these months in 2020 compared with 2019, the estimates were substantially smaller than those seen in our analysis of the full cohort. GPH scores were consistent or slightly better in January and February 2020 than the corresponding months in 2019, which further strengthens our physical health findings in the full cohort.

There are, however, a number of limitations that should be considered. First, differences in PROMIS GH during the COVID-19 pandemic could be explained by many factors that we were unable to account for in this observational study, such as reason for the office visit. Second, the vast majority of patients completed the PROMIS GH through MyChart during the pandemic, which could inadvertently limit the type of patients included in this study. Nevertheless, results remained consistent in a sensitivity analysis restricted to patients who completed the PROMIS GH electronically through MyChart in both periods. Third, PROMIS GH is an overall measure of HRQOL and may not be sensitive to the unique stressors of COVID-19. Fourth, our results are from 1 healthcare system in northeast Ohio and may not be generalizable to all patients. Some areas within the United States may have been more or less affected by state and local policies, which could differentially influence HRQOL. Our study also includes only patients who completed the PROMIS GH and are not representative of all patients. COVID-19 is disproportionately affecting racial and ethnic minority groups and low income populations, who have less access to healthcare and receive poor quality care.⁴⁵ Our study demonstrated black patients and those with the lowest quartile of income had worse HRQOL overall, yet not differentially worse during the pandemic. HRQOL may be substantially different in patients not included in this study. Finally, there were too few patients who had a positive test result for COVID-19 during our

study window to evaluate the impact of COVID-19 itself on HRQOL, and this is also outside the scope of this article.

Conclusion

We found modest decreases in GMH and similar GPH during the COVID-19 pandemic compared with 1 year earlier in patients seen in a large healthcare system. Nevertheless, the type of patients seeking ambulatory healthcare during the pandemic warrants consideration. Outcomes studies using EHR data and self-reported HRQOL should be aware of these biases when interpreting results. Findings from our study have important implications for the impact of the pandemic on self-reported HRQOL and the interpretation of aggregate measures of HRQOL during these months.

Supplemental Material

Supplementary data associated with this article can be found in the online version at https://doi.org/10.1016/j.jval.2021.06.009

Article and Author Information

Accepted for Publication: June 4, 2021

Published Online: July 31, 2021

doi: https://doi.org/10.1016/j.jval.2021.06.009

Author Affiliations: Department of Quantitative Health Sciences, Lerner Research Institute (Lapin, Honomichl, Hogue); Center for Outcomes Research and Evaluation, Neurological Institute (Lapin, Honomichl, Katzan); and Department of Cardiovascular Medicine, Sydell and Arnold Miller Family Heart, Vascular, and Thoracic Institute (Tang), Cleveland Clinic, Cleveland, OH, USA.

Correspondence: Brittany R. Lapin, PhD, MPH, Department of Quantitative Health Sciences, Lerner Research Institute, Cleveland Clinic, 9500 Euclid Ave, Cleveland, OH 44195, USA. Email: lapinb@ccf.org

Author Contributions: Concept and design: Lapin, Tang, Katzan Acquisition of data: Lapin

Analysis and interpretation of data: Lapin, Honomichl, Hogue, Katzan Drafting of the manuscript: Lapin, Tang, Honomichl, Hogue, Katzan Critical revision of the paper for important intellectual content: Lapin, Tang, Honomichl, Hogue, Katzan Statistical analysis: Lapin, Honomichl

Conflict of Interest Disclosures: Dr Tang reported being a consultant for Sequana Medical AG and Owkin Inc and receiving an honorarium from Springer and the American Board of Internal Medicine outside of the submitted work. No other disclosures were reported.

Funding/Support: The authors received no financial support for this research.

REFERENCES

- Rumsfeld JS, Alexander KP, Goff Jr DC, et al. Cardiovascular health: the importance of measuring patient-reported health status: a scientific statement from the American Heart Association. *Circulation*. 2013;127(22):2233– 2249.
- Katzan IL, Thompson NR, Lapin B, Uchino K. Added value of patient-reported outcome measures in stroke clinical practice. J Am Heart Assoc. 2017;6(7): e005356.
- Basch E, Deal AM, Dueck AC, et al. Overall survival results of a trial assessing patient-reported outcomes for symptom monitoring during routine cancer treatment. *JAMA*. 2017;318(2):197–198.
- Calvert M, Blazeby J, Altman DG, et al. Reporting of patient-reported outcomes in randomized trials: the CONSORT PRO extension. JAMA. 2013;309(8):814–822.
- 5. U.S. Department of Health and Human Services FDA Center for Drug Evaluation and Research, U.S. Department of Health and Human Services FDA

Center for Biologics Evaluation and Research, U.S. Department of Health and Human Services FDA Center for Devices and Radiological Health. Guidance for industry: patient-reported outcome measures: use in medical product development to support labeling claims: draft guidance. *Health Qual Life Outcomes*. 2006;4:79.

- Mayo NE. Dictionary of Quality of Life and Health Outcomes Measurement. 1st ed. Milwaukee, WI: International Society for Quality of Life Research; 2015.
- Evans JP, Smith A, Gibbons C, Alonso J, Valderas JM. The National Institutes of Health Patient-Reported Outcomes Measurement Information System (PROMIS): a view from the UK. Patient Relat Outcome Meas. 2018;9:345–352.
- 8. Blumenthal KJ, Chang Y, Ferris TG, et al. Using a self-reported global health measure to identify patients at high risk for future healthcare utilization. *J Gen Intern Med.* 2017;32(8):877–882.
- **9.** Seneviratne MG, Bozkurt S, Patel MI, et al. Distribution of global health measures from routinely collected PROMIS surveys in patients with breast cancer or prostate cancer. *Cancer*. 2019;125(6):943–951.
- Kobau R, Cui W, Zack MM. Adults with an epilepsy history fare significantly worse on positive mental and physical health than adults with other common chronic conditions-estimates from the 2010 National Health Interview Survey and Patient Reported Outcome Measurement System (PROMIS) Global Health scale. *Epilepsy Behav.* 2017;72:182–184.
- Barile JP, Reeve BB, Smith AW, et al. Monitoring population health for Healthy People 2020: evaluation of the NIH Promis(R) Global Health, CDC Healthy Days, and satisfaction with life instruments. *Qual Life Res.* 2013;22(6):1201–1211.
- Kirzinger A, Kearney A, Hamel L, Brodie M. KFF health tracking poll early April 2020: the impact of coronavirus on life in America. KFF. https://www. kff.org/coronavirus-covid-19/report/kff-health-tracking-poll-early-april-202 0/. Accessed January 15, 2021.
- Park CL, Russell BS, Fendrich M, Finkelstein-Fox L, Hutchison M, Becker J. Americans' COVID-19 stress, coping, and adherence to CDC guidelines. J Gen Intern Med. 2020;35(8):2296–2303.
- Moreno C, Wykes T, Galderisi S, et al. How mental health care should change as a consequence of the COVID-19 pandemic [published correction appears in Lancet Psychiatry. 2021;8(7):e16]. *Lancet Psychiatry*. 2020;7(9):813–824.
- Li J, Yang Z, Qiu H, et al. Anxiety and depression among general population in China at the peak of the COVID-19 epidemic. World Psychiatry. 2020;19(2):249–250.
- 16. Wang C, Pan R, Wan X, et al. Immediate psychological responses and associated factors during the initial stage of the 2019 coronavirus disease (COVID-19) epidemic among the general population in China. Int J Environ Res Public Health. 2020;17(5):1729.
- 17. Gao J, Zheng P, Jia Y, et al. Mental health problems and social media exposure during COVID-19 outbreak. *PLoS One*. 2020;15(4):e0231924.
- **18.** Fullana MA, Hidalgo-Mazzei D, Vieta E, Radua J. Coping behaviors associated with decreased anxiety and depressive symptoms during the COVID-19 pandemic and lockdown. *J Affect Disord*. 2020;275:80–81.
- **19.** Qiu J, Shen B, Zhao M, Wang Z, Xie B, Xu Y. A nationwide survey of psychological distress among Chinese people in the COVID-19 epidemic: implications and policy recommendations [published correction appears in Gen Psychiatr. 2020;33(2):e100213corr1]. *Gen Psychiatr.* 2020;33(2):e100213.
- González-Sanguino C, Ausín B, Castellanos MÁ, et al. Mental health consequences during the initial stage of the 2020 coronavirus pandemic (COVID-19) in Spain. Brain Behav Immun. 2020;87:172–176.
- Smith L, Jacob L, Yakkundi A, et al. Correlates of symptoms of anxiety and depression and mental wellbeing associated with COVID-19: a crosssectional study of UK-based respondents. *Psychiatry Res.* 2020;291:113138.
- Serafini G, Parmigiani B, Amerio A, Aguglia A, Sher L, Amore M. The psychological impact of COVID-19 on the mental health in the general population. *QJM*. 2020;113(8):531–537.
- 23. Ettman CK, Abdalla SM, Cohen GH, Sampson L, Vivier PM, Galea S. Prevalence of depression symptoms in US adults before and during the COVID-19 pandemic. *JAMA Netw Open.* 2020;3(9):e2019686.
- 24. Rudenstine S, McNeal K, Schulder T, et al. Depression and anxiety during the COVID-19 pandemic in an urban, low-income public university sample. *J Trauma Stress.* 2021;34(1):12–22.

- Katzan I, Speck M, Dopler C, et al. The Knowledge Program: an innovative, comprehensive electronic data capture system and warehouse. AMIA Annu Symp Proc, 2011;2011:683–692.
- Global Health a brief guide to the PROMIS®Global Health instruments. Patient-Reported Outcomes Measurement Information System. http://www. healthmeasures.net/images/PROMIS/manuals/PROMIS_Global_Scoring_Manual. pdf. Accessed April 26, 2021.
- Hays RD, Bjorner JB, Revicki DA, Spritzer KL, Cella D. Development of physical and mental health summary scores from the patient-reported outcomes measurement information system (PROMIS) global items. *Qual Life Res.* 2009;18(7):873–880.
- Liu H, Cella D, Gershon R, et al. Representativeness of the Patient-Reported Outcomes Measurement Information System Internet panel. J Clin Epidemiol. 2010;63(11):1169–1178.
- Meaningful change for PROMIS®. HealthMeasures. https://www. healthmeasures.net/score-and-interpret/interpret-scores/promis/meaningfulchange. Accessed January 15, 2021.
- Charlson ME, Pompei P, Ales KL, MacKenzie CR. A new method of classifying prognostic comorbidity in longitudinal studies: development and validation. *J Chronic Dis.* 1987;40(5):373–383.
- **31.** Yuan Y, Yung YF, Stokes M. Propensity score methods for causal inference with the PSMATCH procedure. Cary, NC: SAS Institute Inc; 2017.
- **32.** Yang D, Dalton JE. A unified approach to measuring the effect size between two groups using SAS®. SAS Global Forum; 2012.
- Nguyen TL, Collins GS, Spence J, et al. Double-adjustment in propensity score matching analysis: choosing a threshold for considering residual imbalance. BMC Med Res Methodol. 2017;17(1):78.
- 34. Lamm M, Yung YF. Estimating causal effects from observational data with the CAUSALTRT procedure. Cary, NC: SAS Institute Inc; 2017.
- Tang F, Liang J, Zhang H, Kelifa MM, He Q, Wang P. COVID-19 related depression and anxiety among quarantined respondents. *Psychol Health*. 2021;36(2):164–178.
- Verma S, Mishra A. Depression, anxiety, and stress and socio-demographic correlates among general Indian public during COVID-19. Int J Soc Psychiatry. 2020;66(8):756–762.
- **37.** Brooks SK, Webster RK, Smith LE, et al. The psychological impact of quarantine and how to reduce it: rapid review of the evidence. *Lancet*. 2020;395(10227):912–920.
- O'Neil A, Nicholls SJ, Redfern J, Brown A, Hare DL. Mental health and psychosocial challenges in the COVID-19 pandemic: food for thought for cardiovascular health care professionals. *Heart Lung Circ*. 2020;29(7):960– 963.
- Mattioli AV, Sciomer S, Cocchi C, Maffei S, Gallina S. Quarantine during COVID-19 outbreak: changes in diet and physical activity increase the risk of cardiovascular disease. *Nutr Metab Cardiovasc Dis.* 2020;30(9):1409–1417.
- 40. Scotté F, Minvielle E, Mir O, André F, Barlesi F, Soria JC. A patient reported outcome platform, a useful tool to improve monitoring and effective management of Covid-19-positive patients with cancer. Eur J Cancer. 2020;132:1–4.
- **41.** Perrin PB, Rybarczyk BD, Pierce BS, Jones HA, Shaffer C, Islam L. Rapid telepsychology deployment during the COVID-19 pandemic: a special issue commentary and lessons from primary care psychology training. *J Clin Psychol.* 2020;76(6):1173–1185.
- 42. Scott Kruse C, Karem P, Shifflett K, Vegi L, Ravi K, Brooks M. Evaluating barriers to adopting telemedicine worldwide: a systematic review. *J Telemed Telecare*. 2018;24(1):4–12.
- Miller CJ, McInnes DK, Stolzmann K, Bauer MS. Interest in use of technology for healthcare among veterans receiving treatment for mental health. *Telemed J E Health*. 2016;22(10):847–854.
- Czeisler MÉ, Marynak K, Clarke KEN, et al. Delay or avoidance of medical care because of COVID-19-related concerns - United States, June 2020. MMWR Morb Mortal Wkly Rep. 2020;69(36):1250–1257.
- **45.** Kantamneni N. The impact of the COVID-19 pandemic on marginalized populations in the United States: a research agenda. *J Vocat Behav.* 2020;119: 103439.